



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NTP Research Report on the CLARITY-BPA Core Study; Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces a meeting to peer review the Draft NTP Research Report on the CLARITY-BPA Core Study. This report presents the results of the core, guideline-compliant, chronic, extended-dose-range study of bisphenol A (BPA) in rats conducted as part of the CLARITY-BPA Research Program. The U.S. Food and Drug Administration's National Center for Toxicological Research (NCTR) conducted the study under the auspices of the National Toxicology Program and prepared the draft report in collaboration with the National Institute of Environmental Health Sciences (NIEHS). The peer-review meeting will be held at NIEHS in Research Triangle Park, NC and is open to the public. Registration is requested for attendance at the meeting either in-person or by webcast and to present oral comments. Information about the meeting and registration is available at <https://ntp.niehs.nih.gov/go/rrprp>.

DATES:

Meeting: Tentatively scheduled for April 26, 2018, 8:30 a.m. to adjournment at approximately 5:00 p.m. Eastern Daylight Time (EDT). The meeting may end earlier or

later than 5:00 p.m. EDT. The preliminary agenda of topics is available at <https://ntp.niehs.nih.gov/go/rrprp> and will be updated one week before the meeting.

Document Availability: The draft NTP Research Report should be available by February 23, 2018, at <https://ntp.niehs.nih.gov/go/rrprp>.

Written Public Comment Submissions: Deadline is April 12, 2018.

Registration for Oral Comments: Deadline is April 12, 2018.

Registration to Attend Meeting In-person or to View Webcast: Deadline is April 26, 2018.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Webpage: The draft NTP Research Report, preliminary agenda, registration, and other meeting materials will be available at <https://ntp.niehs.nih.gov/go/rrprp>.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Camden Byrd, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293-1660, Fax: (919) 293-1645, Email: NTP-Meetings@icf.com.

SUPPLEMENTARY INFORMATION:

Background: Bisphenol A (BPA) is a chemical produced in large quantities for use primarily in the production of polycarbonate plastics and epoxy resins. BPA also is used in the production of certain flame retardants and as a color developer in some thermal paper. BPA has been detected in air, soil, water, landfill leachate, and the human body.

The primary source of human exposure to BPA is thought to be through the diet. More than 800 studies were published on the health effects of BPA between the mid-1990s and the mid-2000s. Although BPA is a well-studied chemical, few existing, chronic toxicity studies have included exposure during the perinatal period. There is also inconsistency among BPA toxicological studies with regard to findings and their interpretation for human health. Given the uncertainty regarding the potential health effects from BPA exposure, NTP, NIEHS, and U.S. Food and Drug Administration (FDA) established the consortium-based research program, called Consortium Linking Academic and Regulatory Insights on Toxicity of BPA (CLARITY-BPA).

The aim of the CLARITY-BPA program was to attempt to bridge guideline-compliant research conducted at the FDA with hypothesis-based research investigations conducted by academia on the toxicity of BPA. A detailed description of the CLARITY-BPA program has been published (<https://www.ncbi.nlm.nih.gov/pubmed/26232693>). The CLARITY-BPA research program has two components: 1) A “core,” guideline-compliant, chronic study conducted at NCTR according to FDA Good Laboratory Practice (GLP) regulations (2-year perinatal only or chronic BPA exposure, including perinatal), and 2) CLARITY-BPA grantee studies of various health endpoints, conducted by NIEHS-funded researchers at academic institutions using animals born to the same exposed pregnant rats as the core GLP study.

The draft NTP Research Report presents the results of the core GLP chronic study. The interpretation of biological and toxicological responses described in the draft NTP Research Report is based only on the results of the core GLP study. Integration of these data with other data from the grantee-studies conducted as part of the CLARITY-

BPA research program or extrapolation of the results to other species, including characterization of hazards and risks to humans, is outside of the scope of the draft NTP Research Report.

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment; in-person attendance at NIEHS is limited by the space available (~100 attendees). Registration for in-person attendance is on a first-come, first-served basis. After the first 100 registrants, persons will be placed on a wait list and notified should an opening become available. Registration to attend the meeting in-person or view the webcast is by April 26, 2018, at <https://ntp.niehs.nih.gov/go/rrprp>. The URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in person is available at <https://www.niehs.nih.gov/about/visiting/index.cfm>. Individuals with disabilities who need accommodation to view the webcast should contact Camden Byrd by phone: (919) 293-1660 or email: NTP-Meetings@icf.com. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

Public Comment Registration: NTP invites written and oral public comments on the draft NTP Research Report. Guidelines for public comments are at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

The deadline for submission of written comments is April 12, 2018. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice

will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific or technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

The agenda allows for one oral public comment period (12 commenters, up to 5 minutes per speaker). Registration to provide oral comments is on or before April 12, 2018, at <https://ntp.niehs.nih.gov/go/rrprp>. Registration is on a first-come, first-served basis. Each organization is allowed one time slot. Oral comments may be presented in person at NIEHS or by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. After the maximum number of speakers is exceeded, individuals registered to provide oral comment will be placed on a wait list (6 slots on wait list) and notified should an opening become available. Commenters will be notified after April 12, 2018, the deadline to register for oral public comments, about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Camden Byrd by email: NTP-Meetings@icf.com by April 12, 2018.

Meeting Materials: The draft NTP Research Report and preliminary agenda will be available on the NTP website at <https://ntp.niehs.nih.gov/go/rrprp>. The draft NTP Research Report should be available by February 23, 2018. Additional information will be posted when available or may be requested in hardcopy; contact Camden Byrd by phone: (919) 293-1660 or email: NTP-Meetings@icf.com. The preliminary meeting agenda is available on the meeting web page and will be updated one week before the

meeting. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an “as needed” basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Camden Byrd by email: NTP-Meetings@icf.com. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: February 7, 2018.

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National Toxicology Program.

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